Remarks

Claim Rejections – 35 U.S.C. § 103

In the current Office Action, the pending claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cherkuri et al. (U.S. Pat. 5,980,704) in view of Chang (U.S. Pat. 4,591,570). According to the Patent Office, "Cherkuri et al. teach a cassette/fluid array (device tray) including micron-sized reservoirs, connected microchannels (fluid delivery system), and reaction cells etched into a substrate. . . . The reference does not teach a non-uniform micropatterned chemical array." With respect to the secondary reference, the Patent Office stated, "Chang teaches an immunoassay device comprising a pattern or array of minute antibodycoated spots on the surface of a support. Each spot is made up of antibodies of different and distinct specificity (abstract). The reference does not teach a plurality of wells defining the space between the cell binding location and the fluidic location." Based on these two references, the Patent Office concluded as follows: "It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the non-uniform micropatterned chemical array of Chang with the device of Cherkuri because one would have had a reasonable expectation of success in depositing spots of antibody as in Chang in the wells of the device of Cherkuri to bind various antigens." The applicant respectfully traverses this rejection and submits that the Office has not established a prima facie case of obviousness.

The MPEP outlines three essential criteria that <u>must</u> be met to establish a *prima facie* case of obviousness:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations.

MPEP § 2143 (citing In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991)). In addition, "the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." *Id.* Moreover, the burden of establishing a prima facie case of obviousness is on the Patent Office. In re Bell, 991 F.2d 781 (Fed. Cir. 1993). Accordingly, "if the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness." MPEP § 2142.

The first element of the *prima facie* case is absent: a suggestion or motivation to combine the references. Cherkuri discloses a microfluidic device for use in combinatorial chemical synthesis while Chang discloses a glass cover slip support containing an array of antibody-containing spots. One of skill in the art would have had no motivation to combine Cherkuri and Chang because the two devices described in these two references are so completely unrelated—one device relates to chemical synthesis while the other relates to immunoassays. Furthermore, the Patent Office has not pointed to any suggestion—either implicit or explicit—in either reference that one device can or should be combined with the other. According to the MPEP, "When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper." See MPEP § 2142. We respectfully submit that the Patent Office has failed to establish the first element of the prima facie case.

The second element of the *prima facie* case of obviousness, a reasonable expectation of success, is similarly absent. According to the Federal Circuit, a prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that lead one of skill in the art away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). In this case, Cherkuri teaches away from the claimed invention:

The center distribution plate 310 having a complex network of distribution microchannels, reservoirs and various feeds, is made preferably from silicon. The techniques for etching silicon are well known in the art which make silicon a preferred substrate for etching a complex distribution network. However, once etched, the silicon substrate is also pretreated to eliminate surface adsorption of proteins and related bio-materials.

Cherkuri, column 6, lines 35-42 (emphasis added). If one of skill in the art were to follow this teaching, it would be impossible to adhere antibodies (which are proteins) to the device of Cherkuri. Therefore, the Patent Office's statement in the current Office Action that "one would have had a reasonable expectation of success in depositing spots of antibody as in Chang in the wells of the device of Cherkuri to bind various antigens" is simply untrue. Indeed, the portion of Cherkuri quoted above also bears on the first element of the *prima facie* case because by leading one <u>away</u> from combining Chang and Cherkuri it diminishes any motivation to combine.

Finally, the third element of the *prima facie* case, that every claim limitation must be taught or suggested by the prior art, is absent as well. In the current Office Action, the Patent Office stated that Chang "does not teach a plurality of wells defining the space between the cell binding location and the fluidic location." In two previous Office Actions on this application—those mailed on 9/18/01 and 6/4/02—the Patent Office stated that Cherkuri "does not teach a plurality of wells defining the space between the cell binding location and the fluidic location." However, in direct contradiction of its previous Office Actions, the Patent Office asserts that the Applicants' argument that Cherkuri does not teach a fluid delivery system comprising a plurality of domains matching the wells on the surface of the base is erroneous (Page 3, point 5 of the Office Action). The Patent Office does not acknowledge that this assertion represents a contradiction of its position in previous Office Actions, but instead points to Column 3 lines 21-41 of the Cherkuri reference. The Patent Office again appears to be ignoring the recited limitations of claim 1, wherein a "well" is defined as a "cell binding site", and wherein the "cell

binding sites" are positions on a surface with a "non-uniform micropatterned chemical array" that support cell binding. Nothing in the Cherkuri passage cited by the Patent Office, nor elsewhere in Cherkuri, teaches or suggests the use of a non-uniform micropatterned chemical array to support cell binding on the bottom plate disclosed in Cherkuri. Furthermore, as discussed above, Cherkuri teaches devices for combinatorial chemistry, and specifically teaches treating the device so as to eliminate surface deposition of proteins and related bio-materials (column 6, lines 35-42), which those of skill in the art would understand to include cells. Thus, not only does Cherkuri not teach this limitation, it teaches away from it. In combination with the Patent Office's admission that Chang does not teach this limitation, it is clear that the combination of references cited by the Patent Office does not teach at least this element of the claims.

In summary, the applicant respectfully submits that the Office has failed to establish any of the three elements of the *prima facie* case of obviousness with respect to claim 1 of the pending application. Furthermore, the Patent Office has not even analyzed any of the remaining claims, and thus has not established a prima facie case of obviousness with respect to pending claims 9-22. Accordingly, we respectfully request withdrawal of the § 103 rejection.

Conclusion

In view of the remarks above, the application is considered to be in good and proper form for allowance. Therefore, the Patent Office is respectfully requested to pass the application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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